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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,984	08/29/2003	Itzhak Bentwich	050992.0300.CPUS09	1983
37808	7590	07/25/2007		
ROSETTA-GENOMICS				
c/o PSWS				
700 W. 47TH STREET				
SUITE 1000				
KANSAS CITY, MO 64112				
EXAMINER				
VIVLEMORE, TRACY ANN				
ART UNIT		PAPER NUMBER		
1635				
MAIL DATE		DELIVERY MODE		
07/25/2007		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/604,984	BENTWICH, ITZHAK	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2007 and 17 May 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 21 and 41-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 21 and 41-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/07</u>  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection or objection not reiterated in this Action is withdrawn.

### ***Drawings/Specification***

The drawings are objected to because the specification indicates at paragraphs 59-60 that the application contains 3297 figures, however the specification as filed contains only 14 figures. The compact discs submitted with the application do not appear to contain these figures; the artifacts available to the examiner contain the sequence listing and Tables 1 and 2. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required

corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21 and 41-49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 10, 13 and 14 of copending Application No. 10/535,164. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to SEQ ID NOs: 4641 and 4642, disclosed by the instant specification as a bioinformatically detectable gene. The claims of the '164 application are directed to bioinformatically detectable gene sequences having the structural limitations of the instant claims. Therefore, the instant claims are a species of and would anticipate the generic claims of the '164 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 21 and 41-49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 8, 11 and 12 of copending Application No. 10/605,838. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to SEQ ID NOs: 4641 and 4642, disclosed by the instant specification as a bioinformatically detectable gene. The claims of the '838 application are directed to bioinformatically detectable gene sequences having the structural limitations of the

instant claims. Therefore, the instant claims are a species of and would anticipate the generic claims of the '838 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Furthermore, the following serial numbers of co-pending applications contain claims in which an obviousness-type double patenting rejection might be applied or contain claims for which it cannot be determined if the claimed sequences conflict:  
11/511,035 11/384,049 11/709,691 10/708,953 10/536,560 10/605,840 10/709,572  
10/709,739 11/130,649 10/604,985 10/605,923 10/707,003 10/707,147 10/707,975  
10/708,204 10/708,951 10/708,952 11/418,870 10/604,726 10/604,926 10/604,943  
10/604,945.

It is Applicants' burden to file appropriate terminal disclaimers for all relevant applications listed above. Furthermore, if Applicants are aware of any pending applications or patents, which are not listed above, it is Applicants' duty to disclose these applications or patents, and to submit an appropriate terminal disclaimer over these applications or patents as pertinent to the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

In response to the obviousness-type double patenting rejections, in the remarks filed 4/16/07 applicants state the belief that the only outstanding rejections are

obviousness-type double patenting rejections, which will allow the examiner to withdraw the provisional rejections and convert each to a double patenting rejection in the co-pending cases. In view of the instant application being filed earlier than the cited applications, Applicant respectfully requests that the obviousness-type double patenting rejection be withdrawn pursuant to MPEP 804.I.B.1.

This argument is not persuasive because in view of the current rejections these are not the only outstanding rejections. However, even if this were the case, not all of the outstanding provisional rejections are against applications filed after the instant application. Any provisional ODP to an application filed earlier than the instant application is not automatically withdrawn when it is the only remaining rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21 and 41-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are directed to isolated nucleic acids of 18-24 or 50-120 nucleotides in length that comprise at least 18 nucleotides of SEQ ID NOs: 4642 or 4641, the RNA

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equivalent or complement of the nucleic acid or a sequence at least 62.5%, at least 70.8% or at least 79.2% identical to the sequence of at least 18 nucleotides of SEQ ID NOs: 4642 or 4641.

The claims encompass any nucleic acid sequence up to 120 nucleotides in length sharing at least 62.5% identity with sequences comprising at least 18 nucleotides of SEQ ID NOs: 4642 or 4641, a large genus of sequences defined only by a minimum identity with sequences comprising a portion of the recited SEQ ID NOs. The specification discloses at paragraph 42972 that VGAM precursor 3152 produces several different shorter precursor RNAs that are further processed to produce sequences including the 24 nucleotide sequences identified as SEQ ID NOs: 4642 and 4641. Applicants state in the remarks submitted May 17, 2007 that figures 1930D/1 and 1931D/1 show that these 24mers are capable of binding to different genes, forming complexes having 15, 17 or 19 nucleotides complementary to the target gene. As noted above in the objection to the drawings, no such figures are present in the application file, however even if it is assumed these figures are present in the specification, based on applicants remark it does not appear they would provide written description support for the claimed limitations. While it is acknowledged the recited SEQ ID NOs appear able to bind to different target genes with varying degrees of complementarity, these examples of alignments with target genes do not demonstrate that the specification provides written description support for the claims as amended. The specification does not appear to contemplate as part of the invention a genus of sequences having some minimum degree of identity with the claimed SEQ ID NOs.



### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz, can be reached on 571-272-0763. The central FAX Number is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight

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(EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore  
Examiner  
Art Unit 1635

TV  
July 19, 2007

A handwritten signature in black ink, appearing to read 'R. Schnizer', with a long horizontal line extending to the right.

RICHARD SCHNIZER, PH.D.  
PRIMARY EXAMINER